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Explanatory note

Interim Order Respecting the Importation, Sale and Advertising of Drugs for Use in Relation to COVID-19

(This note is not part of the Order.)

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Proposal

The *Interim Order Respecting the Importation, Sale and Advertising of Drugs for Use in Relation to COVID-19* (the Interim Order) was signed by the Minister of Health on September 16, 2020. The Interim Order allows for the issuance of an expedited authorization for the importation, sale and advertising of drugs used in relation to COVID-19; this includes both human and veterinary drugs. It allows the Minister to account for urgent public health needs relating to COVID-19 in deciding whether to authorize a COVID-19 drug based on the provided evidence of safety, efficacy, and quality. The Interim Order also allows establishment licences to be issued in relation to COVID-19 drugs in a more agile manner, taking into consideration urgent public health needs, and provides a mechanism for the Minister to allow the Public Health Agency of Canada (PHAC) to import promising COVID-19 drugs for placement (pre-positioning) in Canadian facilities prior to their authorization in Canada.

The Interim Order was made under subsection 30.1(1) of the *Food and Drugs Act* (the Act), which allows the Minister to make temporary interim orders if the Minister believes that immediate action is required to deal with a significant risk, direct or indirect, to health, safety or the environment.

Without an Order in Council approving it, the Interim Order would, in accordance with paragraph 30.1(2)(a) of the Act, cease to have effect 14 days after it was made. An Order in Council would enable the operation of the Interim Order, allowing it to remain in effect for up to one year after it is made.

Objectives

The objective of the Interim Order is to expedite the authorization for the importation, sale, and advertising of drugs used in relation to COVID-19 while taking into consideration urgent public health needs. It also provides an option for establishment licences to be issued in relation to COVID-19 drugs in a more agile manner. The Interim Order further provides the ability for the Chief Public Health Officer of PHAC to notify the Minister of a need to pre-position a promising COVID-19 drug in Canada. In order for a drug to be pre-positioned, the Government of Canada must have entered into a contract for its procurement and the manufacturer must have filed an application for the drug's authorization in Canada, or abroad with a foreign reference regulator. Together, these measures help ensure Canadians have timely access to COVID-19 drugs.

Background

COVID-19 is a new disease not previously identified in humans. It is an infectious respiratory disease caused by the most recently discovered coronavirus, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). COVID-19 infection has been known to cause respiratory symptoms, fever, cough, shortness of breath, and breathing difficulties. In more severe cases, it may cause pneumonia, severe acute respiratory syndrome, kidney failure, and death. The World Health Organization declared a global

pandemic related to COVID-19 on March 11, 2020. There are now more than 26 300 000 cases, in at least 185 countries, and over 860 000 people have lost their lives. ¹ The number of confirmed cases in Canada as of September 3, 2020 has exceeded 130 000; ² however, the situation is changing rapidly.

Many pharmaceutical companies and academic institutions worldwide are developing candidate vaccines and potential treatments and therapies for COVID-19. While these new drugs and vaccines are being developed to specifically address COVID-19, pharmaceutical companies are looking at the potential of using already approved and marketed drugs, such as broad-spectrum antivirals and anti-inflammatory drugs. Expedited authorization of drugs for use in relation to COVID-19 will allow these medically necessary drugs to be made available quickly for Canadians.

Prior to a product being available on the Canadian market, Health Canada reviews product information to confirm the requirements of the *Food and Drugs Act* and its associated regulations are met. Based on the information provided, the Department assesses the risks and benefits of the product to ensure Canadians have access to products that are safe, effective and of high quality. In addition, any person who fabricates, packages, labels, imports, tests, distributes, or wholesales a drug for sale in Canada must hold an establishment licence issued under the *Food and Drug Regulations* .

On March 18, 2020, the Minister of Health published a notice entitled, "Expedited Review of Health Product Submissions and Applications to address COVID-19". This notice outlined Health Canada's intent to expedite the authorization of a vaccine and other therapies for COVID-19 as they become available.

Implications

The Interim Order introduces expedited authorization pathways for the importation, sale and advertising of drugs used in relation to COVID-19. The authorization of a drug under the Interim Order is predicated on the Minister's determination that the evidence provided supports the conclusion that the benefits outweigh the risks associated with the drug, taking into account the uncertainties related to the benefits and risks, as well as the urgent public health need caused by COVID-19. This includes weighing the risks of modifying certain requirements for information to support the safety and effectiveness of a drug, such as allowing consideration of a foreign regulatory approval, against the benefits of having it available to Canadians quickly.

The Interim Order introduces expedited authorization pathways for drugs with a COVID-19 indication that are not yet authorized in Canada or other jurisdictions; as well as COVID-19 drugs that are authorized for sale by a foreign regulatory authority. In addition, the Interim Order provides a mechanism to permit the sale of a drug that is already authorized in Canada under this Interim Order or the *Food and Drug Regulations*, for indications related to COVID-19 that are not included in the drug's authorization.

Although COVID-19 is understood to be primarily a human disease, COVID-19 is a new disease and its impacts on animal health may not be fully known at this time. To date, there have not been any reports of livestock contracting COVID-19 and early information from a small number of studies suggests pigs, chickens and ducks are not susceptible to the virus. However, there have been several reports of infected humans spreading the virus to their pet dog or cat; therefore, out of an abundance of caution, veterinary drugs were included in the scope of the Interim Order.

Drugs not authorized in Canada or by a foreign regulatory authority

The Interim Order introduces an expedited pathway for the authorization of a new COVID-19 drug by providing more agile application and administrative requirements than what is offered under division 8 of the *Food and Drug Regulations*.

The Interim Order provides the Minister with the ability to take into consideration the uncertainties and the urgent public health needs in the context of the COVID-19 pandemic while determining if a drug demonstrates that its benefits outweigh its risks. Instead of providing detailed reports of the tests establishing the safety of a new drug and substantial evidence of clinical effectiveness as required by the *Food and Drug Regulations*, the Interim Order requires an applicant to submit the known information with respect to the safety and effectiveness of a COVID-19 drug.

In addition, in order to expedite the review process for drug applications submitted for authorization under the Interim Order, a more agile approach has been included to allow an applicant to file further information throughout the course of the review as it becomes available, also known as a rolling application. If using this rolling application approach, the applicant must submit a plan outlining how and when they will provide the Minister with the required information or data that is outstanding.

Drugs authorized by a foreign regulatory authority

In order for a drug to be eligible to use the expedited pathway for drugs that are authorized by a foreign regulatory authority, the drug must be included on the List of Foreign Drugs, which is maintained by the Minister

and incorporated by reference in the Interim Order. A drug may be included on this list if it has been shown to provide benefit in the context of the COVID-19 pandemic, and it has received an authorization for sale in a foreign jurisdiction. The Minister may become aware of such drugs through interactions with international counterparts or environmental scanning, including dialogues with health care providers or potential drug applicants.

In order to be imported, sold, or advertised in Canada, a drug included on the list must still be authorized under the Interim Order; however, the applicant can leverage this foreign regulatory approval and submit a more abbreviated application. The applicant must submit evidence that the drug is authorized for sale in a foreign jurisdiction and sign an attestation that, if requested, all of the information used to authorize the drug by the foreign regulatory authority will be made available to the Minister.

With respect to the foreign drug, the Minister must still determine that all criteria outlined in the Interim Order have been met and, in the context of the COVID-19 pandemic, the benefits of authorizing this drug outweigh the risks.

Expanded indication of drugs authorized in Canada

The Interim Order permits a drug that is already authorized in Canada to be advertised and sold for an expanded indication related to COVID-19. This will be done by the addition of the drug to the incorporated by reference *List of New Drugs for Expanded Indication*. Unlike for an amendment under the *Food and Drug Regulations*, this process can be initiated without an application from the manufacturer.

Additions to this list will be based on environmental scanning by Health Canada, including dialogues with health care providers, as evidence supporting the use of existing drugs in the context of COVID-19 becomes

available. However, an external applicant may make the Minister aware of a drug that may qualify for this process.

As a drug qualifying for this process will already hold an authorization through the Interim Order or the *Food and Drug Regulations*, there will already be known evidence to support its safety, efficacy (for other indications) and quality. In addition, the inclusion of a drug to this list will allow the Minister to request any information the authorization holder may have pertaining to the COVID-19 indication. Any additional information provided on the COVID-19-related indication is also included on the incorporated by reference list.

Drug establishment licences and good manufacturing practices

The Interim Order introduces an option for drug establishment licences to be issued or amended to include the conduct of activities in relation to COVID-19 drugs. This balances the need for flexibilities, such as the modification of certain good manufacturing practices requirements, while still protecting the health and safety of Canadians who will use these COVID-19 drugs. All drug establishment licence applications submitted in relation to the Interim Order will be processed in an expedited manner. Licensing decisions will consider both the material submitted in the application and the necessity of the drug in addressing urgent COVID-19-related health needs.

Labelling, advertising, and reporting requirements

In order to maintain bilingual labelling requirements in accordance with the *Official Languages Act*, the Interim Order ensures the appropriate sections of the *Food and Drug Regulations* will still apply to COVID-19 drugs.

These drugs are also subject to similar advertising prohibitions, as well as adverse drug reaction reporting and recall and shortages reporting requirements, as drugs authorized under the *Food and Drug Regulations*.

Terms and conditions

The Interim Order allows the Minister to impose or amend terms and conditions, and request additional information, in relation to a COVID-19 drug submission, authorization, or establishment licence, at any time while it is in effect. In light of the severity of the COVID-19 pandemic, this allows the Minister to act quickly to gather important safety information or mitigate risk in a timely manner.

Suspension or cancellation

When expediting the authorization of a drug in relation to COVID-19 through the Interim Order, with the goal of enabling timely access to drugs in relation to COVID-19, Health Canada will continue to ensure that these products are supported by sufficient evidence of safety, efficacy and quality. Health Canada will monitor the safety and effectiveness of these drugs and will take immediate action, including the suspension or cancellation of authorizations or establishment licences, if required, to protect the health and safety of Canadians.

Intellectual property

The Interim Order does not include explicit intellectual property protections for innovative drugs submitted for authorization through this process. However, Health Canada will ensure that an innovative drug is able to receive data protection, if and when an authorization is issued under the *Food and Drug Regulations* or another transitional mechanism, by ensuring an authorization for a drug and its medicinal ingredients issued

under the Interim Order is not considered a previous approval for the purposes of defining an innovative drug under section C.08.004.1 of the *Food and Drug Regulations*; and stipulating that a submission cannot be made under the *Food and Drug Regulations* for a new drug, in respect of a COVID-19 claim, based on a direct or indirect comparison to a COVID-19 drug authorized under the Interim Order.

In addition, to maintain incentives for manufacturers of COVID-19 drugs and to ensure the accessibility of these drugs, an application for an authorization based on the direct or indirect comparison to another COVID-19 drug will only be accepted if that other drug is not available on the Canadian market in sufficient quantities to address urgent public health needs related to COVID-19. Prior to a person submitting an application based on a direct or indirect comparison to another drug, they must notify the Minister of their intent to file and provide information demonstrating that the drug being compared to has been issued an authorization under the Interim Order or a Notice of Compliance and is not available in sufficient quantities. The Minister is then required to notify the manufacturer of the drug it is being compared to so the manufacturer can make representations to the Minister as to whether or not it is available in sufficient quantities. If the Minister determines that the drug being compared to is not available in sufficient quantities, the application can be submitted.

Authorization period and fees

Authorizations issued under, and drug establishment licences issued in relation to, the Interim Order are only valid while the Interim Order is in effect. The review of drug applications submitted under the Interim Order will not be subject to cost recovery fees, nor will fees be charged for establishment licence applications submitted in relation to the Interim

Order if the application meets the conditions specified in the *Establishment Licence Fees Remission Order (Indication of an activity in respect of a COVID-19 Drug)*. In addition, the annual fee to sell a product on the Canadian market will not apply to COVID-19 drugs.

Release of clinical information

Health Canada will make publicly available the safety and efficacy evidence relied upon to issue an authorization under the Interim Order. Clinical information will be released for non-commercial purposes and will have all personal information and confidential business information protected prior to publication on Health Canada's Clinical Information Portal.

Pre-positioning

In order to facilitate timely access to promising COVID-19 drugs, the Interim Order introduces a mechanism for the Minister to allow the importation of promising COVID-19 drugs for placement in Canadian facilities prior to their market authorization in Canada, referred to as pre-positioning. This mechanism may be used to import a promising COVID-19 drug into Canada if the Chief Public Health Officer of Canada has notified the Minister of a need to pre-position a COVID-19 drug and the Government of Canada has a procurement agreement for the purchase of the drug. In addition, the manufacturer of the drug must have filed an application for market authorization with Health Canada under the Interim Order or the *Food and Drug Regulations*, or filed an application for market authorization with a foreign regulatory authority.

The Chief Public Health Officer of Canada must also provide a description of the drug to be pre-positioned, which includes the quantity of the drug to be imported into Canada, information regarding the drug's manufacturer, the proposed Canadian drug establishment licence holder that will import

and pre-position the drug, and the facilities where the drug is to be stored. This establishment licence holder could be PHAC, which operates the National Emergency Stockpile System (NESS); the manufacturer itself, which has the contractual agreement with the Government of Canada; or an establishment licence holder identified by the Chief Public Health Officer of Canada.

Guidance and resources

The guidance document entitled "Information and Application Requirements for Drugs Authorized Under the Interim Order Respecting the Importation, Sale and Advertising of Drugs for Use in Relation to COVID-19", outlines the regulatory requirements and other important information for manufacturers wishing to submit an application for authorization through the Interim Order. In addition, Health Canada will publish a list of COVID-19 drug applications received and a list of COVID-19 drugs authorized under the Interim Order. These lists, along with the List of Foreign Drugs and the List of New Drugs for Expanded Indication, will be made publicly available on the Government of Canada website.

Consultation

Canadians have been informed of the expedited review of COVID-19 drug submissions and applications through the Notice entitled, "Expedited Review of Health Product Submissions and Applications to address COVID-19", published on March 18, 2020. Through various other communications, members of the federal health portfolio, provincial and territorial governments, industry associations, and other stakeholders have been made aware, and are supportive of this action to expedite the authorization of COVID-19 drugs.

Three engagement sessions with health care system partners took place between April 30 and May 15, 2020. Stakeholders invited included hospital associations, national advisory committees, the Pan-Canadian Pharmaceutical Alliance, and provincial and territorial drug plan managers, among others. An information session with industry and industry association stakeholders was held on June 25, 2020, with over 80 participants attending, including BIOTECanada and Innovative Medicines Canada. Additional targeted sessions were held on July 2, 2020, to engage the Canadian Animal Health Institute, and July 24 and August 11, 2020, to engage innovative drug manufacturers. The intent of these sessions was to inform these key stakeholders about the details of the Interim Order, to identify measures to ensure its efficient implementation, to discuss future transition measures under consideration for when the Interim Order ceases to have effect, and to provide stakeholders with an opportunity to ask questions.

Participants of all sessions were generally supportive of the Interim Order and the proposed measures. Innovative drug manufacturers, however, raised concerns regarding the absence of protections for innovative products and intellectual property and proposed changes to alleviate these concerns. Health Canada subsequently modified the Interim Order based on these suggestions.

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Footnotes

- 1 [COVID-19 Dashboard by the Center for Systems Science and Engineering \(CSSE\) at Johns Hopkins University \(JHU\)](#)
 - 2 [Coronavirus disease \(COVID-19\): Outbreak update](#)
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